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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. 02N-0278: Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, 68 Fed. Reg. 5328 (Feb. 3, 2003)

To Whom It May Concern:

Herbalife International of America, Inc. ("Herbalife") is submitting these comments to the Food and Drug Administration ("FDA") in response to the February 3, 2003 Proposed Rule "Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002," 68 Fed. Reg. 5428 (Feb. 3, 2003).

For over 23 years, Herbalife has marketed scientifically formulated conventional food, dietary supplements and personal care products through a network of independent distributors in 57 countries worldwide. Each of our 150 products is produced to our exacting specifications by specially selected domestic or international contract manufacturers. Today, our gross annual sales are nearly $2 billion.

Currently, sixteen contract domestic manufacturers produce a majority of the conventional food and dietary supplement products that Herbalife markets in the United States through its network of independent distributors. Additionally, two Canadian-based contract manufacturers produce other conventional food and dietary supplement products we import for sale in the United States through our network of independent distributors. Also, 30 percent of our conventional food and dietary supplements that is sold in 56 international markers originates with production in the United States. Finally, we estimate that between 20-25 percent of all the raw ingredients used by our domestic contract manufacturers originates overseas.

Herbalife recognizes the importance of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 and supports FDA's efforts to collect information relevant to tracking potential bioterrorist events.

02N-0278 C133

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However, the company believes the rule should exempt from notice provisions samples of raw ingredients and finished product (including conventional food and dietary supplements) brought into the U.S. for evaluation product development by our research and development scientists, or that may be imported for evaluation as part of our demanding quality assurance assessment process.

Herbalife believes that global companies such as ourselves would be hard-pressed to meet many of the deadlines for notice as outlined in the Proposed Rule unless we converted our transportation and manufacturing departments to operating 24 hours per day, 7 days per week. Therefore, Herbalife asks FDA to modify these requirements to more accurately reflect the realities of importing food and of doing business in the U.S.

I. Sample Shipments of Food for Research and Development Purposes Should Be Exempt from Prior Notice Requirement

As written, the prior notice requirement outlined in the Proposed Rule is, in our view, overly broad:

> prior notice requirements apply to all food that is brought across the U.S. border . . . regardless of whether the food is intended for consumption in the United States. In other words, FDA believes that food that is brought into the United States to be put into foreign trade zones, or for transshipment or reexport immediate or otherwise, is "imported or offered for import" and thus must comply with the prior notice requirements. 68 Fed. Reg. 5430.

The only exemptions FDA contemplated apply to the food that individual travelers carry in their personal baggage for personal use, as well as food subject to the U.S. Department of Agriculture's ("USDA") exclusive jurisdiction under the Federal Meat Inspection Act, Poultry Products Inspection Act or the Egg Products Inspection Act.

While Herbalife recognizes the importance of tracking the movement of conventional food, dietary supplements and raw ingredients entering the U.S., the company urges FDA to add another exemption from the notice requirement for food (i.e., conventional food and dietary supplements), as well as for food ingredients, imported purely for product development (e.g., research and development) or for assessment by quality assurance professionals. Such exempted samples would not be intended for consumption or further distribution.

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Each day Herbalife receives unsolicited samples of raw ingredients or prototype finished products from vendors hoping to do business with our Company. Many of these raw ingredient samples or product prototypes arrive at our offices without our prior knowledge and without having been requested. It is unclear how such unsolicited commercial samples would be handled given the current prior notice provision.

Almost daily Herbalife colleagues overseas send our California-based staff samples of raw ingredients and/or finished goods for evaluation or testing. These samples or finished goods generally are not intended for consumption nor are they intended for further distribution. These international samples are shipped to our U.S. quality assurance staff for evaluation in response to foreign consumer complaints or in anticipation of quality assurance testing necessary so that the Company may respond to inquiries by foreign regulators. Additionally, foreign suppliers may send Herbalife food ingredients for the purpose of evaluation by research and development. Finally, foreign finished good manufacturers routinely send our quality assurance lab retained samples of consumer products in accordance with our stringent manufacturing standard operating procedures. It would be unduly burdensome if FDA required us to file a prior notice in advance of each of these thousands of shipments.

In each of the cases cited above, the exclusive purpose of the shipment is research and development or lab analysis, and not consumption, distribution, or even further export. Thus, these products have no bearing on the U.S. food supply, and should not be the subject of prior notice requirements.

We urge the FDA to exempt R&D/QA samples from the registration and prior notice provision of the Act in the same manner as are products brought in by individuals for personal consumption. In the case of individual importation, the products are for the individual's private use and not for further distribution to others. Similarly, the R&D/QA samples discussed above are brought into the country for the Company's private use, and not for consumption or distribution to any further parties.

Requiring the company to file prior notices for every R&D/QA sample being shipped in, no matter how small, would require Herbalife and other companies to incur significant new administrative burdens and costs. Herbalife assumes FDA did not intend to create such burdens and asks FDA to clarify its position by adding an exemption for samples imported purely for R&D/QA and evaluative purposes, providing such samples clearly are labeled as such.

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II. Prior Notice Filing Time Should Be Four Hours Prior to Shipment Arrival for Truck and Air Imports

FDA's proposed rule requires that prior notice be given to the agency no later than noon on the calendar day before the food is due to arrive at a U.S. port of entry. Proposed §1.286.

This requirement is not practical for air imports where the contents of the shipment often are not determined nor communicated to the importer until the cargo has departed. These standard operating procedures by carriers make compliance with FDA's Proposed Rule impossible. Herbalife believes that requiring notice four hours in advance would more accurately reflect the reality of air and truck import.

Even if carriers significantly reorganized normal business operations so that contents of shipments were determined well in advance, FDA's proposed requirement is not practicable nor is it workable. Businesses such as ours generally operate on a 5 day/week, 8 hour/day schedule. To ensure that notice was regularly submitted by noon on the prior calendar day, personnel would need to be present seven days a week, 365 days a year in order to ensure that international shipment notices were submitted by the deadline. For small importers, in particular, this requirement would be unduly prohibitive.

We believe that a four hour prior notice requirement would allow those using air carriers to have the information necessary to file a complete notification with FDA. Therefore, Herbalife strongly urges FDA to shorten the deadline for prior notice to four hours prior to arrival at a U.S. port of entry.

III. FDA Should Permit Arrival Updates Up to Arrival Time

FDA is proposing a two-hour minimum deadline for arrival updates submitted under proposed §1.294. Arrival updates may provide the following information:

1. A change in the port of entry;

2. A delay of more than 3 hours in the anticipated time of arrival;

3. An arrival time of more than 1 hour earlier than anticipated; or

4. Grower identity, if not known when original notice was submitted.

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Herbalife does not believe the two-hour window is practical for air shipments. Based on our 23 years of experience, carriers often do not inform importers of changes in arrival time until the cargo is close to its destination. Given the current state of air and travel security, arrivals are rarely at their scheduled times.

Moreover, the two-hour deadline does not take into consideration that arrival times may change outside of normal business operating hours (i.e. 8 AM to 5 PM). The importer may, therefore, not have access to the altered arrival information within the timeframe required by FDA. In this sense, compliance with FDA's deadline would require importers to run a 24 hour/day operation which simply is not feasible for many small operations.

Herbalife urges FDA to modify this requirement so that updates are required by the arrival time. This would allow companies to respond to delayed information coming from carriers and still adequately provide timely information to FDA about when shipments are arriving.

IV. FDA Should Allow for A Broader Array of Amendments and Updates

The Proposed Rule permits only a very narrow range of changes to a prior notice, once it is filed. Permitted changes include amendments to product identity information, as described in proposed §1.290, and updates to anticipated arrival information, as outlined in proposed §1.294. If other information provided in the prior notice changes, FDA requires the importer to cancel the prior notice in the FDA Prior Notice System and submit a new prior notice to FDA. Proposed §1.289.

Herbalife believes that this limitation is impractical. It is likely that companies filing numerous prior notices will inadvertently make clerical errors in other portions of the highly detailed filing, such as telephone or fax numbers, Customs ACS entry line numbers, or U.S. Customs entry type.

It does not make sense to ask importers to reenter three pages of product information in a new prior notice in order to correct what may be simple clerical errors. Such a requirement would be burdensome both to importers and ultimately to the FDA Prior Notice System. Herbalife therefore urges FDA to be more flexible in its approach.

V. International Agents Should Be Permitted to File Notices

FDA has limited the range of those authorized to file a prior notice to:

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> A purchaser or importer of an article of food who resides or maintains a place of business in the United States, or an agent who resides or maintains a place of business in the United States acting on the behalf of the U.S. purchaser or importer. Proposed §1.285.

Herbalife believes that FDA should expand this section to also allow an appointed international agent to file the prior notice on the behalf of the importer. An appointed international agent would be in possession of all necessary information and, therefore, could complete the prior notice as accurately as U.S.-based importers. Moreover, an international agent would not negate the fact that the U.S.-based importer remains a responsible party, available for FDA inquiries if the need arises.

The availability of internationally based agents would facilitate the submission of prior notices at times outside of normal U.S. business hours. In this sense, expanding the range of possible filers would alleviate some of the problems raised by the deadlines included in the Proposed Rule.

Herbalife believes in the goals of food safety outlined in by the Public Health Security and bioterrorism Preparedness and Response Act of 2002 and FDA's Proposed Rule. However, the Company asks that FDA add an exemption to the prior notice requirement for samples imported for R&D/QA evaluative purposes. In addition, Herbalife urges FDA to modify its deadlines, types of amendments/updates permitted, and allow international agents to complete the filings. These changes would make the prior notice process more efficient and less burdensome to the regulated industry.

Respectfully submitted,

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